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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,870	02/28/2001	Xavier Forceville	569J US 3770	3493

466 7590 04/18/2003

YOUNG & THOMPSON
745 SOUTH 23RD STREET 2ND FLOOR
ARLINGTON, VA 22202

EXAMINER

PAK, JOHN D

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 04/18/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/763,870

Applicant(s)
Forceville et al.

Examiner
John Pak

Art Unit
1616



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jan 16, 2003
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23, 24, 26-36, and 38-43 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23, 24, 26-36, and 38-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5 6) ☐ Other:

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Claims 23-24, 26-36, 38-43 are now pending in this application.

Claims 23-24, 26-36 and 38-40 are rejected under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Upon reconsideration, and in view of applicant's arguments of 1/16/03, It is confusing in these claims what is encompassed by "mg/kg." It is common practice in the selenium supplementation art to indicate mg/kg for kg of delivery substrate (e.g. feed) or kg of body weight. Since the invention here turns on the dosage, it is critical that applicant uses clear language for the dosage feature.

Claim 39 is confusing and unclear when read in light of claim 35. Claim 35 already has a first treatment of a **daily dose** of 0.025-1 mg/kg selenium and a second treatment of a **daily dose** of 0.00625-0.025 mg/kg selenium. The daily dose language implies that the first and second treatment could encompass more than one day of treatment under the "first treatment" regimen and the "second treatment" regimen. The fact that claim 35 has two daily dose regimen without any specific language as to when such daily dose is supposed to end for first treatment and proceed to the second treatment is somewhat unclear. Add to that the claim 39 feature wherein the initial higher daily dose of 0.025-1 mg/kg is repeated, it would be unclear to the skilled artisan when and how all these different daily doses are intended to be utilized.

Similarly, claim 27 is somewhat confusing because it basically repeats the daily dose of claim 23 as a "subsequent treatment." How would one skilled in the art know when the original treatment of "daily dose" in claim 23 has ended and the treatment has proceeded to the "subsequent treatment" of claim 27?

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It is noted that claim 34 is included in this ground of rejection – claim 34 was indicated in the last Office Action as an allowable dependent claim, which was dependent on a rejected independent claim. Claim 34 does not cure the deficiency of the independent claim, as noted above, and therefore, it must be included here.

Claims 41-43 are rejected under 35 USC 102(b) as being anticipated by
Chemical Abstracts 122:104635

Chemical Abstracts 122:104635 expressly discloses a capsule that contains 1000 IU vitamin E and 3 mg Se. Even though the cited reference does not specifically disclose the capsule for administration to patients suffering from SIRS or any state corresponding to a severe acute attack of an inflammatory pathology causing an exacerbation of cytokine secretion, the composition claimed by applicant and the composition disclosed by the cited reference contain the same ingredients; and the two compositions per se cannot be differentiated. A prior art composition that contains the same ingredients as the claimed composition must necessarily possess the same properties. The claims are thereby anticipated.

Claims 41-43 are rejected under 35 USC 102(b) as being anticipated by
Chemical Abstracts 116:150492

Chemical Abstracts 116:150492 expressly discloses an injection formulation that contains 36 mg selenium (6 mg/ml X 6 ml) and 816 IU vitamin E. Even though the cited reference does not specifically disclose the injection formulation for administration to patients suffering from SIRS or any state corresponding to a severe acute attack of an inflammatory pathology causing an exacerbation of cytokine secretion, the composition

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claimed by applicant and the composition disclosed by the cited reference contain the same ingredients; and the two compositions per se cannot be differentiated. A prior art composition that contains the same ingredients as the claimed composition must necessarily possess the same properties. The claims are thereby anticipated.

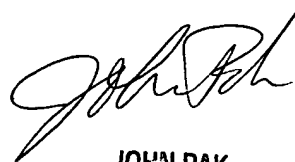
For these reasons no claim can be allowed at this time.

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machines are (703) 308-4556 or (703) 305-3592.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Examiner Pak whose telephone number is (703) 308-4538. The Examiner can normally be reached on Monday through Friday from 7:30 AM to 5:00 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. José Dees, can be reached on (703) 308-4628.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.



JOHN PAK
PRIMARY EXAMINER
GROUP 1600